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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,636	10/20/2003	Patrick Rambaud	0501-1017-1	1794

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EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,636

Applicant(s)

RAMBAUD, PATRICK

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6, 7, 11-14 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 8-10, 15-24, and 30-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date Oct. 20, 2003
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

APPLICANT'S ELECTION

Applicant's election with traverse of Group I (Claims 1-24) in the reply filed on 03/15/06 is acknowledged. Applicant's election with traverse of Specie I-A, II-I, III-A, and IV-C, filed 3/15/2006, is acknowledged. The traversal is on the ground(s) that all species are "encompassed" by the generic claims, thus it would not be burdensome to search and examine all species. Applicant's arguments are not persuasive as the species are mutually exclusive and distinct, as set forth in the restriction requirement mailed 11/15/2005.

Claims 27-31 were added by amendment in the response filed 4/19/06. Applicant's argument set forth in the response is that it would not be burdensome to examine claims 27-31 with claims 1-25. It is noted that applicant elected claims 1-24 in the response filed 3/15/06. This is not found persuasive because newly submitted claims 27-29 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 27 recites steps directed to obtaining from the collected batches a personal library...characterized using cell surface markers. Therefore, claim 27 recites a different mode of operation than that recited in instant claims 1-24 (MPEP § 806.04, MPEP § 808.01). Furthermore, the examination process requires a search of non-patent literature, U.S. patent publications, U.S. patents, as well as foreign patent literature. The requirement is still deemed proper and is therefore made FINAL.

Claims 3, 6, 7, 11-14, and 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the replies filed on 3/15/05 and 04/19/2006.

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CLAIMS UNDER EXAMINATION

Claims 1, 2, 4, 5, 8-10, 15-24, and 30-31 are herein under examination. Claims 25-26 have been cancelled.

IDS

The IDS filed 10/20/2003 has been considered in full.

ABSTRACT

The abstract of the disclosure is objected to because it is not in narrative form and contains multiple paragraphs. In addition, the reference to a "Figure" in the abstract is improper. Correction is required. See MPEP § 608.01(b).

CLAIM REJECTIONS - 35 USC §112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 5, 8-10, 15-24 and 30-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below which leads to the determination that the above claim lacks enablement due to undue experimentation being required to make and use the invention.

In the instant case, the claimed subject matter lacks enablement for the following reasons: Claim 1 requires (i) processing measurements made on samples, (ii) processing status-characterizing information for determining the subject's identity data, (iii) performing an identification of batches of cells by consulting a cell management system, and (iv) determining parameters of a deferred-use protocol for immunocompetent cells using an expert system.

With regard to above steps (i), (ii), and (iii), automated and integrated systems containing protocols for collecting samples, processing measurements made on biological samples, and identifying samples are well known in the art [Zhang et al., *Anal. Chem.*, 1999, Vol. 71, p.1138-1145]. However, step (ii) differs from the prior art in that it requires processing of status-characterizing information for determining a subject's identity data. The specification fails to disclose or provide working examples as to how status-characterizing information and immunity information stored in the immunocompetent cells is processed to determine a subject's identity data, as in instant claims 1 and 4. [Wands factors (2), (3)]. Furthermore, the parameters of a

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deferred-use protocol determined in step (iv), above, are determined by processing successively collected subject's identity data acquired in step (ii). However, the specification does not fully describe or define a subject's "identity data," such that one skilled in the art would know what data this consists of. Furthermore, the specification does not teach how to process this information in order to determine identity data or how to determine the parameters of a deferred-use protocol. Therefore one of ordinary skill in the art would not know how to determine "parameters" for a deferred use protocol.

With regard to step (iv) above, the prior art teaches the development of an expert system for oncology protocol management [Shortliffe et al., In Proc. Seventh International Joint Conference on Artificial Intelligence, 1981, Vol. 60, pp. 876-881], but these protocols are not applicable for the instant claims as the prior art is silent with regard to expert systems or protocols for determining data from "batches of immunocompetent cells." The expert system (ONCOCIN) taught by Shortliffe et al. recites a patient knowledge based that was developed from patient diagnosis, laboratory test, and specific treatment protocol information. Furthermore, the system required the development of a unique data structure to guide knowledge acquisition [35.4.2] and [Fig. 35-3]. In particular, parameters used in the expert system are determined from specific attributes of patient data [35.4.2, ¶ 3]. Shortliffe et al. have encoded knowledge from oncology patients. As each type of cancer requires specific diagnostic and prognostic protocols, it is unlikely that these protocols are directly applicable for deferred-use protocols for immunocompetent cells.

Given the nature of the instantly claimed invention, an expert system would need to be developed to determine the parameters necessary for use in the claimed deferred-use protocol. Sufficient information and guidance is required to develop, test, and validate such an expert system, as supported by the teaching of the prior art, above. Although the level of skill in the art

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of culturing cells and measuring cell parameters is high, as no guidance has been given with regards to steps (ii) and (iv), as discussed in detail above, one skilled in the art would require undue experimentation to predictably practice the instantly claimed invention. [Wands factors (1), (2), (6), (7)].

VAGUE AND INDEFINITE

Claims 1, 2, 4, 5, 8-10, and 15-24 and 30-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to a "method for managing batches of immunocompetent cells." However, instant claim 1 results in "providing said cell treatment entity with said identified batches of cells and with said deferred-use protocol parameters." Therefore it is unclear in what way the steps of instant claim 1 achieve the purpose of the preamble. Clarification is requested. Furthermore, it is unclear if the method is attempting to determine which (if any) of the successive batches can be re-used at some future point in time under certain conditions, or for a particular medical condition, or something else. Clarification is requested.

Claim 1 recites steps directed to (a) conditioning and preserving cells AND; (b) constituting and enhancing a personal library; (c) collecting information; (d) processing information; (e) storing data; (f) performing identification; (g) determining parameters AND; (h) providing batches of cells and parameters. As both step (a) and step (g) recite the term "and", it is unclear which steps of instant claim 1 are required by the claimed method. For example, it is

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unclear if steps (a) and (b) required, or are steps (a) and (b)-(h), or something else. Clarification is requested.

Claim 1 recites the limitation "constituting and enhancing...a personal library." It is unclear if the applicant intends for these to be active method steps or a limitation of the personal library. If applicant intends for these to be active method steps, it is unclear as to who or what is doing the "constituting" and the "enhancing." Clarification is requested. Furthermore, the term "enhancing" is a relative term of degree. Therefore, it is unclear as to what degree the library undergoes "enhancing" before it is considered to be enhanced. Clarification is requested.

Claim 1 recites the limitation "said status-characterizing...collecting being effected." It is unclear if the applicant intends "being effected" to be an active method step or a limitation of the collecting step. In either case, it is unclear in what way the said "information collecting" is "effected." Correction is requested.

Claim 1 recites the limitation "storing, all along said steps." It is unclear whether "all along" is referring to time (i.e. continuous storing throughout each of the steps), data (i.e. all data), or something else. Correction is requested.

Claim 1 recites the limitation "the subject's identify data." There is lack of antecedent basis for this limitation. Correction is requested.

Claim 1 recites the limitation "upon a request for re-use..., performing..., and receiving...". It is unclear as to what is being requested for re-use. Correction is requested. Furthermore, it is unclear if "upon a request for re-use" is an active method step or a limitation of the method steps directed to performing and receiving. Clarification is requested.

Claim 2 recites "(Vincent's bioelectronic method)." The use of parentheses renders it unclear whether the limitation in the parentheses is intended to be a positive limitation of the claim. Due to the use of a proper name, it is further unclear whether the name used to identify

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the method is a tradename or trademarked term. It is noted that use of tradenames render claims indefinite as such names can change over time or may be used to refer to a plurality of different methods, and it is unclear what steps are intended to be encompassed by the tradenamed method. Clarification is requested.

Claim 5 recites "said expert system is arranged for providing an interpretation...with respect to a particular gene." It is unclear what limitation of the expert system is intended by its "arrangement." Secondly, it is unclear whether this is an actual method step or a further limitation of the expert system. Clarification is requested.

Claim 16 recites "before the step for cryo-preserving." However, there is lack of antecedent basis for a step of cryo-preserving in claim 1. Claim 16 also recites "in view of annihilating antibodies." It is unclear in what way "in further view of annihilating antibodies" further limits the method step. Clarification is requested.

Claim 19 recites "in view of determining..." throughout. The limitation is confusing in this context because claim 19 is directed to a system and not a method. Therefore it is unclear in what way "in view of determining" is intended to limit the system. Clarification is requested.

Claim 22 recites "capillary study on elements of said...hair system." It is unclear whether "elements" is intended to mean actual chemical elements, information elements, or otherwise. Clarification is requested.

Claim 23 recites "means for controlling and enhancing an expert system...in view of determining parameters for deferred-use protocols." It is unknown what structural or functional limitation (i.e. hardware, software) is required to meet the limitations of "controlling and enhancing." Furthermore, the term "enhancing" is a relative term of degree. It is unclear as to the degree to which the system must be enhanced such that the said means is considered to be "enhancing." Clarification is requested.

CONCLUSION

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

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MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
7/24/06